EMA/931898/2011

European Medicines Agency decision

P/0029/2012

of 30 January 2012

on the acceptance of a modification of an agreed paediatric investigation plan for semuloparin sodium (EMEA-000562-PIP01-09-M01) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

Disclaimer

This Decision does not constitute entitlement to the rewards and incentives referred to in Title V of Regulation (EC) No 1901/2006.

Only the English text is authentic.

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on the acceptance of a modification of an agreed paediatric investigation plan for semuloparin sodium (EMEA-000562-PIP01-09-M01) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

The European Medicines Agency,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No. 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004[1],

Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency[2],

Having regard to the European Medicines Agency's decision P/54/2010 issued on 7 April 2010,

Having regard to the application submitted by Sanofi-aventis Recherche & Développement on 3 October 2011 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a deferral and a waiver,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 13 January 2012, in accordance with Article 22 of Regulation (EC) No 1901/2006,

Having regard to Article 25 of Regulation (EC) No 1901/2006,

Whereas:

(1) The Paediatric Committee of the European Medicines Agency has given, following a re-examination procedure of the Paediatric Committee's opinion according to Article 25(3) Regulation (EC) No 1901/2006, an opinion on the acceptance of changes to the agreed paediatric investigation plan.

(2) It is therefore appropriate to adopt a decision on the acceptance of changes to the agreed paediatric investigation plan.

[1] OJ L 378, 27.12.2006, p.1.
[2] OJ L 136, 30.4.2004, p. 1.

Has adopted this decision:

Article 1

Changes to the agreed paediatric investigation plan for semuloparin sodium, solution for injection, subcutaneous use are hereby accepted in the scope set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices.

Article 2

This decision is addressed to Sanofi-aventis Recherche & Développement, 1, avenue Pierre Brossolette, 91385 Chilly-Mazarin, France.

Done at London, 30 January 2012

For the European Medicines Agency
Guido Rasi
Executive Director
(Signature on file)

EMA/PDCO/35074/2012

Opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan (after re-examination)

EMEA-000562-PIP01-09-M01

Scope of the application

Active substance(s):

Semuloparin sodium

Condition(s):

Thromboembolic events

Pharmaceutical form(s):

Solution for injection

Route(s) of administration:

Subcutaneous use

Name/corporate name of the PIP applicant:

Sanofi-aventis Recherche & Développement

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Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Sanofi-aventis Recherche & Développement submitted to the European Medicines Agency on 3 October 2011 an application for modification of the agreed paediatric investigation plan with a deferral and a waiver as set out in the European Medicines Agency's decision P/54/2010 of 7 April 2010. The application for modification proposed changes to the agreed paediatric investigation plan.

An Opinion was adopted by the Paediatric Committee on 11 November 2011, for the above mentioned product. Sanofi-aventis Recherche & Développement received the Paediatric Committee Opinion on 18 November 2011.

On 15 December 2011 Sanofi-aventis Recherche & Développement submitted to the European Medicines Agency a written request including detailed grounds for a re-examination of the Opinion.

The re-examination procedure started on 16 December 2011.

Scope of the modification

Some measures and timelines of the Paediatric Investigation Plan have been modified.

Final Opinion

1. The Paediatric Committee, having assessed the detailed grounds for re-examination, in accordance with Article 25(3) of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

1.1. to revise its opinion and

- to agree to the changes regarding the measures and timelines of the paediatric investigation plan in the scope set out in the Annex I of this opinion.

The Icelandic and the Norwegian Paediatric Committee members agree with the above-mentioned recommendation of the Paediatric Committee.

2. The measures and timelines of the agreed paediatric investigation plan and the subset(s) of the paediatric population and condition(s) covered by the waiver are set out in the Annex I.

This opinion is forwarded to the applicant and the Executive Director of the European Medicines Agency, together with its annex(es) and appendix.

London, 13 January 2012

On behalf of the Paediatric Committee
Dr Daniel Brasseur, Chairman
(Signature on file)

Annex I

The subset(s) of the paediatric population and condition(s) covered by the waiver and the measures and timelines of the agreed Paediatric Investigation Plan

Condition(s)

Thromboembolic events.

1. Waiver

1.1. Condition

Prophylaxis of venous thromboembolism (VTE) in patients undergoing knee replacement surgery, hip replacement surgery or hip fracture surgery including extended prophylaxis.

The waiver applies to:

- All subsets of the paediatric population from birth to less than 18 years of age;
- for Solution for injection for subcutaneous use;
- on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified paediatric subset(s).

1.2. Condition

Prophylaxis of venous thromboembolism (VTE) in patients undergoing abdominal surgery who are at risk for thromboembolic complications.

The waiver applies to:

- All subsets of the paediatric population from birth to less than 18 years of age;
- for Solution for injection for subcutaneous use;
- on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified paediatric subset(s).

1.3. Condition

Prophylaxis of venous thromboembolism (VTE) in cancer patients undergoing chemotherapy

The waiver applies to:

- All subsets of the paediatric population from birth to less than 18 years of age;
- for Solution for injection for subcutaneous use;
- on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified paediatric subset(s).

2. Paediatric Investigation Plan

2.1. Condition to be investigated

Thromboembolic events.

2.2. Indication targeted by the pip

Prophylaxis of thromboembolism (TE) in pediatric patients with Central Venous Line and additional pro-thrombotic risk factors.

2.3. Subset(s) of the paediatric population concerned by the paediatric development

From birth to less than 18 years of age.

2.4. Pharmaceutical form(s)

Solution for injection.

2.5. Studies

Area	Number of studies	Description
Quality	Total number of quality studies: 1	Study 1: Development of an age-appropriate formulation
Non-clinical	Total number of studies: 0	Not applicable.
Clinical	Total number of studies: 3	Study 2: In vitro assessment of the concentration/activity relationship of semuloparin in paediatric patients from birth to less than 18 years of age. Study 3: open-label, multicentre, multiple dose trial to evaluate pharmacokinetics and safety in hospitalised children from birth to less than 18 years of age with a Central Venous Line (CVL). Study 4: open-label, randomised multicentre trial to evaluate safety and efficacy in children from birth to less than 18 years of age with with a Central Venous Line (CVL) and additional prothrombotic risk factors.

3. Follow-up, completion and deferral of pip

Measures to address long term follow-up of potential safety issues in relation to paediatric use:	No
Date of completion of the paediatric investigation plan:	By October 2018
Deferral for one or more studies contained in the paediatric investigation plan:	Yes